National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Protocol Submission Checklist

Please Print or Type

Name of Institution: _____

Institution Protocol No.: _____ **NCI Protocol No.:** _____

Protocol Chairman: _____ **Phone No.:** _____

List NCI-Supplied Agents: _____

Please indicate type of material enclosed and fill in the blanks:

☐ New Protocol ☐ Revised Protocol ☐ Amendment ☐ Status Notice

I. NEW PROTOCOL ENTITLED:

☐yes ☐no Have you submitted a *Letter of Intent* for this protocol? If yes, what is the LOI No: _____

☐yes ☐no Are you enclosing a signed and dated IRB approval (Form 596)? If no, explain: _____

☐yes ☐no Are you submitting this protocol for approval for CCOP?

☐yes ☐no Is this protocol part of a grant or cooperative agreement? Grant No.: _____

☐yes ☐no Do you wish this protocol to be considered a *contract-funded* study? Contract No.: _____

Projected Date of Activation (If already opened, provide activation date): _____

II. REVISIONS: Response to CTEP questions for protocol awaiting CTEP approval

III. AMENDMENT TO APPROVED PROTOCOL:

☐ ACTIVATION AMENDMENT (List of changes between CTEP approval and local activation)
- ☐ Activation Amendment only (list changes)
- ☐ Activation Amendment plus replacement pages
- ☐ Activation Amendment plus replacement document

☐ AMENDMENT FOR ACTIVE STUDY
- ☐ Editorial, administrative changes
- ☐ Scientific changes
- ☐ Change of participants
- ☐ Change of Protocol Chairman

IV. OFFICIAL NOTICE OF CHANGE IN PROTOCOL STATUS:

- ☐ Activation Date: _____
- ☐ Temporary Closure Date: _____
- ☐ Reactivation Date: _____
- ☐ Closure Date: _____
- ☐ Completion Date: _____

V. OTHER: _____

_____

_____

_____

_____

_____

_____

Signature of person completing the form ***Phone No.*** ***Date***

VI. CORRELATIVE STUDIES (laboratory, pharmacokinetic or other correlative studies).

Are any correlative studies embedded within this protocol? ☐yes ☐no If yes:

A. Correlative Study Identification Code

Each correlative study should have a unique identification code. Please provide a unique code for each correlative study. Correlative study codes should be limited to a maximum of 8 characters (alpha and/or numeric).

Example: Correlative Study Identification Code: P-123.

B. Correlative Study Title

Please indicate the title of each correlative study (laboratory, pharmacokinetic or other correlative studies) embedded within this trial.

Example: Correlative Study Title: O^6-benzylguanine concentrations in plasma.

1. Correlative Study Identification Code: _____

Correlative Study Title: _____

_____

2. Correlative Study Identification Code: _____

Correlative Study Title: _____

_____

3. Correlative Study Identification Code: _____

Correlative Study Title: _____

_____

If additional space is required, please include as an attachment.

VII. SUBGROUP: A subgroup (stratum) is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment.

A. Subgroup Identification Code

Each subgroup should have a unique identification code. Please provide a code for each correlative study. Subgroup codes should be limited to a maximum of 8 characters (alpha and/or numeric). If a protocol has only a single subgroup then all patients will be entered on subgroup "A".

Example: Subgroup Code: A.

B. Subgroup Description

1. Patients stratified by disease: Please indicate what disease(s) will be included in each subgroup. Use International Medical Terminology (IMT) terms. If unsure of the appropriate IMT term please check the CTEP home page for a comprehensive list of IMT terms.
2. Patients stratified by other classification (ex. prior therapy, age): Please describe what patient characteristics (other than disease) will be used to uniformly group patients for treatment or analysis.

Example: Subgroup Description: Patients with previously untreated gliomas.

a. Subgroup Code: _____ *(Use "A" for protocols with a single subgroup)*

Subgroup Description: _____

_____

b. Subgroup Code: _____

Subgroup Description: _____

_____

c. Subgroup Code: _____

Subgroup Description: _____

_____

If additional space is required, please include as an attachment.

VIII. TREATMENT ASSIGNMENT (arm/dose level):

The unique treatment characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each arm or dose level should be considered a distinct treatment assignment.

A. Treatment Assignment Identification Code

Each treatment assignment (arm or dose level) should have a unique identification code. Please provide a code for each treatment assignment included in this study. Treatment assignment codes should be limited to a maximum of 8 characters (alpha and/or numeric). If a protocol has only a single treatment assignment then all patients will be entered on treatment assignment "1".

Example: Treatment Assignment Code: Level 1.

B. Treatment Assignment Description, (Agent(s)/Dose Regimen/Schedule/Route)

Provide a complete description of each treatment assignment. Include the agent name, dose, route and schedule for every agent within a treatment assignment. In addition any non-pharmacologic treatment modality(s) (radiation, surgery, etc.) should also be described.

Example: Treatment Assignment Description:
Cisplatin 100mg/m^2 IV over 1 hour for one dose on day one.
Taxol 130mg/m^2 IV over 3 hours for one dose on day one. Repeat every 21 days.

1. Treatment Assignment Code: _____ *(Use "1" for protocols with one treatment assignment)*

Treatment Assignment Description: _____

2. Treatment Assignment Code: _____

Treatment Assignment Description: _____

3. Treatment Assignment Code: _____

Treatment Assignment Description: _____

4. Treatment Assignment Code: _____

Treatment Assignment Description: _____

If additional space is required, please include as an attachment.